

**REMARKS/ARGUMENTS**

Claims 58-95 are pending in the application. Claims 58-95 are rejected.

Applicants note on the Office Action Summary sheet that it is unclear whether or not the drawings submitted on July 17, 2003 are accepted. Applicants request clarification.

**I. Issues under 35 U.S.C. §112, second paragraph**

Claims 58-95 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for allegedly failing to particularly point out and distinctly claim the inventive subject matter. In particular, the term “intricately shaped” as utilized in the term “three-dimensional intricately shaped” is allegedly indefinite. Applicants respectfully disagree.

The term “intricately shaped” is a known term and is, in fact, definite. For example, the term “intricately shaped” is present in the issued claims of U.S. Patent No. 6,630,153, from which the present application is a divisional claiming priority thereto. The term “intricately shaped” is also present in U.S. Patent No. 6,103,989 and U.S. Patent No. 5,010,133, and even the term “intricate shape” is present in the issued claims of U.S. Patent No. 6,630,153; U.S. Patent No. 4,921,154; U.S. Patent No. 5,053,049; and U.S. Patent No. 4,476,369. Given that at least U.S. Patent No. 6,630,153 concerns subject matter in the art, one of skill therein would readily recognize the term, and it therefore would not be indefinite.

Even if the term were not present in an issued patent, this term is not indefinite in its own right. In paragraph [0064] of the specification, Applicants clearly define the term “three-dimensional intricate shape” as used herein is defined as a shape having projections and/or at least one surface that has a relief profile. Furthermore, the definition of relief profile is found in paragraph [0061] as “a contour on a material having projections and indentations which approximate the contour of the surface which imparts the contour, such as a punch”. Furthermore, an illustrative example of an intricate shape is provided in paragraph [0089], which refers to an exemplary six-armed JAX™ granule as an intricate shape.

Finally, the term “intricate” is defined by [www.dictionary.com](http://www.dictionary.com) as having many complexly arranged elements; elaborate. Therefore, the shape can be construed as having

complexly arranged elements, as opposed to, say, a tablet.

Thus, as the term is known by the skilled artisan and is clearly defined by Applicants, the term is not indefinite, and Applicants respectfully request removal of the rejection.

## **II. Issues under 35 U.S.C. §102(b)**

### **A. U.S. Patent No. 5,614,206**

Claims 58, 59, 62-75, 86-89, and 93-95 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Randolph *et al.* (U.S. Patent No. 5,614,206; "Randolph"). Applicants respectfully disagree.

Randolph teaches calcium sulfate pellets comprising alpha calcium sulfate hemihydrate with a specific particle size of about 1  $\mu\text{m}$  to about 45  $\mu\text{m}$ , and pellets comprising beta calcium sulfate hemihydrate with a specific particle size of about 10 $\mu\text{m}$  to about 15 $\mu\text{m}$ . The pellets taught by Randolph may contain medicaments, and may be formed by molding or pressing. Randolph does not teach a dry powder compaction method.

Applicants teach a three-dimensional intricately shaped bone graft substitute made by dry powder compaction of bone material. Randolph does not teach a dry powder compaction method. Randolph teaches use of calcium hemihydrate, and the pellets formed are by definition not created through a dry process, but rather through a hydrated process. Additionally, Randolph does not teach the creation of three-dimensional intricate shapes but teaches "pellets". A pellet is defined in the Webster dictionary as being a usually small, rounded, spherical or cylindrical body, and this is not an intricate shape.

The Examiner contends that "powder broadly interpreted reads on granules." Even if this were true, Randolph does not teach a dry powder compaction method, and Randolph teaches a pellet and not a substitute having an intricate shape.

Thus, Applicants state that Randolph does not teach all elements of all of the pending claims. Furthermore, this is particularly true for claims 87-95, directed to particular punches, dies, and movability thereof.

"A claim is anticipated only if each and every element as set forth in the claim is

found either expressly or is inherently described in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) (emphasis added). “The identical invention must be shown in as complete detail as is contained in the...claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) (emphasis added). See also MPEP 2131.

Applicants respectfully request withdrawal of this 35 U.S.C. § 102(b) rejection in light of the above arguments.

**B. U.S. Patent No. 5,981,828**

Claims 58, 59, 63-66, 86-89, and 93-95 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Nelson *et al.* (U.S. Patent No. 5,981,828; Nelson). Applicants respectfully disagree.

Nelson teaches a cup produced by an acetabular allograft press, wherein a plunger and bowl are mounted in a loading frame. The acetabular cup composite made of compressed allograft bone and interdigitated cement is for use in patients with acetabular defects (see column 5, lines 23-45). This press is a rack-and-pinion style press which creates the cup-shaped product. The acetabular cup formed by Nelson is created through a process that requires cement, and such a process is necessarily “wet” in nature. Applicants, on the contrary, teach an intricately shaped bone graft substitute made by dry powder compaction method.

Again, Nelson does not teach all elements of all of the pending claims, but this is particularly true for claims 87-95, directed to particular punches, dies, and movability thereof.

Thus, as Nelson does not teach each and every limitation taught by Applicants, there can be no anticipation, and a rejection under 35 U.S.C. § 102(b) is improper.

In light of the above arguments and amendments, Applicants respectfully request

withdrawal of the 35 U.S.C. § 102(b) rejection.

**III. Issues under 35 U.S.C. §103(a)**

**A. U.S. Patent No. 5,614,206**

Claims 76-78 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Randolph. Applicants respectfully disagree.

Randolph teaches a very specific calcium sulfate composition in a pellet having a controllable dissolution rate, methods of delivering medicaments *in vivo* utilizing the pellet, and methods of preparing the pellets. In particular, the powder consists essentially of alpha-calcium sulfate hemihydrate and optionally a second powder consisting essentially of beta-calcium sulfate hemihydrate, both of which have particular purities, BET surface areas, mean particle sizes, and particle size distributions. As the intent of Randolph is to teach methods and compositions for controlled release of a medicament, the process of manufacturing the composition is clearly not the substantive focus of the invention.

Applicants respectfully assert the present invention is not obvious in light of the Randolph reference. There is no suggestion or inclination for an intricately shaped bone graft substitute. In fact, Randolph is particularly silent on the shape the powder is compressed into, other than a pellet, and Applicants assert that this in no way suggests that other shapes should be used or would be beneficial, as that shaped element is a significant advantage in the instant invention. Therefore, the rejection under 37 C.F.R. § 103 is inappropriate. Applicants respectfully state that a claim is considered obvious only if the claimed invention as a whole would have been obvious to a skilled artisan. *In re Mayne*, 104 F.3d 1339, 1342 (Fed. Cir. 1997).

Moreover, although the Examiner contends that one skilled in the art would have been motivated to prepare the molded pellet having medicaments incorporated therein, when relying on a modification of the prior art to reject a claim, it is incumbent upon the Examiner to identify some suggestion *in the prior art* to make the modification. *In re Mayne*, 104 F.3d at 1342 (emphasis added). There is no suggestion by Randolph to modify the pellet to make Applicants' shaped substitute.

Both the Federal Circuit Court and the court of Customs and Patent Appeals have directed the Patent Office to determine if the prior art reference is available 35 U.S.C. § 102 as an enabling reference. See *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed Cir. 1985), *In re LeGrice*, 301 F.2d 939, 133 USPQ 365, 371 (CCPA 1962). The reference must be enabled before it can be applied.

On this note, Applicants contend that Randolph does not teach the present invention and furthermore is not enabled for the same purpose. That is, Examples 1-4 of Randolph teach providing a mold for a slurry of calcium sulfate hemihydrate powder mixed with normal saline, and the slurry is poured into cylindrical molds to make the pellets. The Examples further teach “setting” the samples (“The Vicat set is a measure of the time it takes for a mixture to harden so that it may support a specific mass...”). In Example 5 of Randolph, however, pellet preparation methods were compared. In the Pressed Pellet method, a dry blend of calcium sulfate and tobramycin were mixed, added to sterile saline, and then pressed with a pellet punch and die using 50 psi of pressure until the mix hardened. In the Molded Pellet method, tobramycin was mixed with water, and then the calcium sulfate hemihydrate was added and mixed in a bowl. The mixture was then placed in the mold and given time to harden. Therefore, as this teaches a “wet” manner of making a composition, Applicants assert that the Randolph is not enabled.

Furthermore, patent teaches away from the present invention. Teaching of a “wet” method of making a composition would lead one of skill in the art directly away from the teaching of a dry method. A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, ,220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) Applicants claims are directed to compressing a powdered or granulated bone material into a shape, as opposed to a slurry as taught by Randolph. As an analogy, construction of an object with cement would not render obvious a different object compressed from dry sand. The methods of the instant invention teach turning a purely solid material into a shape by brute force, as opposed to providing a shape for a wet material to harden into.

Also, Applicants note that the claims of the Randolph patent are directed to mixing powders *consisting essentially of* the alpha- or beta-calcium sulfate hemihydrate. This also

teaches away from the instant invention, as Applicants' technology preferably further comprises a processing aid composition to facilitate compaction of the powder and release of a compacted powdered product from a die. The implicit absence of this material from Randolph inherently demonstrates that the inventions are dissimilar enough such that Randolph teaches away for a different purpose and intent altogether.

Applicants also respectfully assert that the Examiner is perhaps mistaking 'obvious' with 'obvious to try.' The "obvious to try" standard has been held to constitute an improper ground for a 35 USC § 103 rejection. *In re O'Farrell*, 858, F.2d 894, 903 (Fed. Cir. 1988). An "obvious-to-try" situation exists when a general disclosure may pique an inventor's curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result or indicate that the claimed result would be obtained if certain directions were pursued. *In re Eli Lilly & Co.*, 902 F.2d 943 (Fed. Cir. 1990). Thus, an invention is not obvious just because it is "obvious to try," such that the prior art gives "only general guidance as to the particular form of the invention or how to achieve it." *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). This is particularly true since it is well established that "there is usually an element of 'obviousness to try' in any research endeavor." *In re Tomlinson, Hall, and Geigle*, 150 USPQ 623, 626 (CCPA 1966)

Finally, Applicants contend that the instant invention provides a solution to a long-felt need in the art. Given that the Randolph patent, directed to pellet formation from a calcium sulfate hemihydrate, issued in 1997, four years passed before filing of Applicants' invention. If the invention is obvious, one would expect others to have taught the invention prior to Applicants' filing.

#### **B. U.S. Patent No. 5,981,828**

Claims 90-92 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Nelson. Applicants respectfully disagree.

Nelson teaches a composition generated by an acetabular allograft press. For the reasons stated above, these compositions and methods are nonidentical to the invention described by Applicants.

There is no teaching or suggestion of intricately shaped bone graft substitutes in Nelson. If Nelson were modified to comprise an intricately shaped bone graft substitute, such a composition would render Nelson unable to function as an acetabular bone graft replacement. Column 1, lines 18-22 in Nelson describe the cup-like shape of the acetabulum. Nelson describes the formation of a cup-like allograft in column 3, line 10. An intricate shape, such as a JAX™, would be inappropriate for use as an acetabular cup substitute. If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)

Absent a teaching or suggestion of all the claim limitations in the prior art, Applicants' invention is nonobvious. Thus, Applicants respectfully request that the rejection of claims 33-35 under 35 U.S.C. § 103(a) be withdrawn.

#### **IV. Conclusion**

Each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

If an outstanding fee is due and has not been paid at any time during prosecution of this application, please charge our Deposit Account No. 06-2375, under Order No. HO-P02125US1 from which the undersigned is authorized to draw.

Dated:

*January 26, 2005*

Respectfully submitted,

By Melissa L. Sistrunk

Melissa L. Sistrunk

Registration No.: 45,579

FULBRIGHT & JAWORSKI L.L.P.

1301 McKinney, Suite 5100

Houston, Texas 77010-3095

(713) 651-5151

(713) 651-5246 (Fax)

Agent for Applicant